March 2, 2009

The Honorable Jonathan Harris Co-Chair, Committee on Public Health Legislative Office Building, Room 3000 Hartford, CT 06106-1591

The Honorable Elizabeth Ritter Co-Chair, Committee on Public Health Legislative Office Building, Room 3004 Hartford, CT 06106-1591

SUBJECT: Testimony in Opposition to SB 1046

Chairmen Harris and Ritter,

IMS Health is an international health information company with its headquarters in Norwalk, Connecticut. We employ approximately 100 people in our Connecticut headquarters and more than 7,000 worldwide. We are here today to testify in opposition to SB 1046, An Act Concerning Restricted Access to Prescription Drug Information. IMS Health would respectfully request that the Committee on Public Health release SB 1046 with an unfavorable report. SB 1046 is unnecessary and would hurt patients, patient care, and would negatively impact the implementation of new health care initiatives.

IMS Health provides services to a diverse range of healthcare stakeholders in the public and private sectors in over 100 countries around the world. Our primary interest is preserving and continually enhancing the critical data assets and the flow of anonymous data that our nation will need to face the serious healthcare challenges ahead, and to inform efforts to improve quality and longevity for our population at an affordable price. We support efforts to protect the privacy of personal health information for patients and application applications to protect the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients are supported by the privacy of personal health information for patients and applications are supported by the privacy of personal health information for patients are supported by the privacy of personal health information for patients are supported by the personal health information for personal health to do so. Our own policies and practices to protect patient privacy include multiple encryption techniques and many overlapping safeguards so that the data we provide to assist healthcare stakeholders in no way allow identification of individual patients.

IMS understands the need to manage healthcare costs. Collectively, our quality of life depends upon it. We applaud efforts to manage utilization and to increase the appropriate use of generics, which now represents over 70% of all prescription products dispensed in this country. Many healthcare reform initiatives are being studied now, and there is a complex set of alternatives and possible solutions under consideration at the state and federal levels such as: HIT, universal healthcare, pay for performance, chronic care management and personal accountability. It is our hope that IMS Health data assets will enable these important efforts and protect patients by optimizing their care with evidencebased information. In the context of the overall healthcare debate, it is clear to us that accurate and timely health care data and information will be absolutely necessary to enable

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these initiatives to succeed. Otherwise, it could be compared to performing surgery while blindfolded.

It is also of great importance to us that the principles that will guide healthcare reform going forward are protected and preserved today. That is why IMS is against data restriction laws, such as SB 1046, which impede the free flow of important information that does not compromise the privacy of individual patients. These legislative proposals undermine the principle of transparency, which is an underlying tenet in healthcare reform. Health care experts, agencies and thought-leaders of political parties as well as AARP, Health care experts, agencies and thought-leaders of political parties as well as AARP, of maintaining transparency.

Legislative efforts to restrict data to specific stakeholders in the healthcare system have been justified by proponents by a shifting set of rationales, with little if any substance in facts. Initially, they were framed by their proponents in the context of patient and physician privacy to garner support and raise the level of fear around this issue when, in fact, no such risk exists. Today, we hear very little about privacy as a basis for data restriction risk exists. Today, we hear very little about privacy as a basis for data restriction legislation. Perhaps this is a result of the fact that two Federal Judges examined the matter legislation. Perhaps this is a result of the fact that two Federal Judges examined there was and decided there is no inherent privacy issue, supporting our contention that there was intentional exaggeration by some of the proponents of these bills in the first place.

When these privacy arguments failed, it was suggested that these laws would reduce costs. This is a popular theme, but to date no information has been provided by proponents of these laws to support such a conclusion; and there is significant information to the contrary these laws to support such a conclusion; and there is significant information to the contrary that suggests marketplace practices already exist to manage costs, without the need for data restrictions that may compromise patient care:

- New Hampshire restricted these data for approximately 9 months in 2006-2007;
 with no reported impact on costs. If the availability of these data drives costs, how does one account for that?
- In Vermont, witnesses for the state indicated that the measurement of any impact from a data restriction law would take years. This would only be the case if these data have only a minimal (if any) impact on costs, requiring sufficient time and numbers to measure?
- The dispensing of new brand medications (products with a market presence of 3 or less years) has declined from 5.7% of total prescriptions dispensed in 2003 to only 1.3% in 2008. At the same time, generic medication grew to represent approximately 70% of dispensed prescriptions in 2008. How would that lead one to conclude that these data were causing physicians to prescribe brand medications in appropriately?
- From 1999 to 2007, the use of prescriber-level data by pharmaceutical research company representatives increased by nearly 56% while the annual rate of prescription drug spend growth plummeted from over 15% to only 1.6%. In 2008, there was a negative growth rate recorded for drug spend.
- Of particular importance, managed prescription programs are much more influential
 in determining what is dispensed. Based on clinical and cost considerations, using
 active formulary management, patient education, tiered co-pays, and offering
 patients lower-cost equivalents (generic or brand) when appropriate, managed

prescription programs continue to lower costs. And they have done so in spite of price increases and a 31% increase in the overall number of prescriptions dispensed

Managed prescription programs are well established and effective in managing utilization and costs. Today, generic prescribing uptake and share have achieved a national average of 70% of dispensed prescriptions. Once again, how would one conclude that payers in the public or private sectors were being over-run by rampant or irrational prescribing practices?

Data restriction bills such as SB 1046 would risk patient care by intentionally impeding the process that brings medical breakthroughs to patients on a timely basis.

Slowing this process effectively delays treatment. That means patients who can benefit from newer medications may be harmed.

This law affects all products regardless of patient benefit. Life-saving medications and documented advances will be impacted the same as marginal improvements. The lives and safety of patients in need of breakthrough treatments for devastating diseases such as cancer, HIV and "orphan" ailments would be jeopardized by the passage of this bill.

Date restriction would undermining application to support risk management programs, without which important medicines may not reach patients.

Proponents of these laws say the medical marketplace will disseminate all the information required for patient care when in fact studies published in the New England Journal of Medicine showed that patients are not routinely treated according to best practices. Further, the Institute of Medicine indicated that dissemination of proven practices throughout the healthcare system can take as long as 17 years, even with these data

In light of these problems and needs, IMS suggests that you are now considering legislation that would remove one of the tools that supports timely dissemination of product information, quality improvement and continuous education.

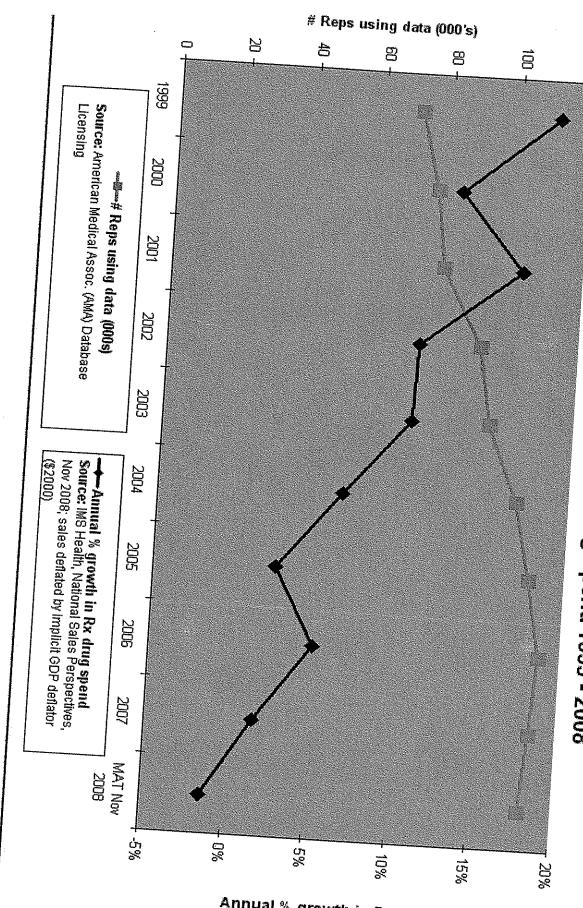
Additionally, SB 1046 risks the health of a robust biotechnology industry:

As members of the bioscience industry attest, these data allow a more efficient process for bringing medical innovation to patients. Without them marketing costs will increase and there will be a need for a relatively larger sales force. This information allows small companies to compete with large companies and fuels the emergent biotech companies that employ small sales forces to reach few physicians...who treat the small populations who may benefit (*The proverbial* needle in a haystack).

Finally, we object to the idea that government should decide who has access to and use of information. Government deciding to block the flow of information because it wants to control behavior represents a very dangerous precedent. Moreover, this type of ill-advised blockade of information has been, just in the last few days, considered and rejected in both In conclusion, IMS believes that Senate Bill #1046, if enacted, will ultimately hurt patients. We urge you to vote against its passage.

Respectfully submitted,

Randolph Frankel Vice President, IMS Health



Growth in Pharmaceutical Rep. Use of Prescriber-level Data vs. Growth Rate in National Rx Drug Spend 1999 - 2008

120

Annual % growth in Rx drug spend

SPECIAL ARTICLE

The Quality of Health Care Delivered to Adults in the United States

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ABSTRACT

We have little systematic information about the extent to which standard processes involved in health care — a key element of quality — are delivered in the United States.

We telephoned a random sample of adults living in 12 metropolitan areas in the United States and asked them about selected health care experiences. We also received written consent to copy their medical records for the most recent two-year period and used this information to evaluate performance on 439 indicators of quality of care for 30 acute and chronic conditions as well as preventive care. We then constructed aggregate scores.

Participants received 54.9 percent (95 percent confidence interval, 54.3 to 55.5) of recommended care. We found little difference among the proportion of recommended preventive care provided (54.9 percent), the proportion of recommended acute care provided (53.5 percent), and the proportion of recommended care provided for chronic conditions (56.1 percent). Among different medical functions, adherence to the processes involved in care ranged from 52.2 percent for screening to 58.5 percent for follow-up care. Quality varied substantially according to the particular medical condition, ranging from 78.7 percent of recommended care (95 percent confidence interval, 73.3 to 84.2) for senile cataract to 10.5 percent of recommended care (95 percent confidence interval, 6.8 to 14.6) for alcohol dependence.

The deficits we have identified in adherence to recommended processes for basic care pose serious threats to the health of the American public. Strategies to reduce these deficits in care are warranted.

From RAND, Santa Monica, Calif. (E.A.M., S.M.A., J.A., J.K., J.H., A.D.); the Veterans Affairs (VA) Greater Los Angeles Health Care System, Los Angeles (S.M.A.); the Department of Medicine, University of California Los Angeles, Los Angeles (S.M.A.); the VA Center for Practice Management and Outcomes Research, VA Ann Arbor Health Care System, Ann Arbor, Mich. (E.A.K.); and the Department of Medicine, University of Michigan, Ann Arbor (E.A.K.). Address reprint requests to Dr. McGlynn at RAND, 1700 Main St., P.O. Box 2138, Santa Monica, CA 90407, or at beth_mcglynn@ rand.org.

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HE DEGREE TO WHICH HEALTH CARE in the United States is consistent with basic quality standards is largely unknown. 1,2 Although previous studies have documented serious quality deficits, they provide a limited perspective on the issue.3-5 Most have assessed a single condition,6,7 a small number of indicators of quality,8,9 persons with a single type of insurance coverage, 10 or persons receiving care in a small geographic area. 11,12 The few national studies have been limited to specific segments of the population, such as Medicare beneficiaries 13-15 or enrollees in managed-care plans16; have focused on a limited set of topics, such as preventive care, 17 diabetes, 18 or human immunodeficiency virus19; or have assessed health outcomes without a link to specific processes involved in care. 20 As a result, we have no comprehensive view of the level of quality of care given to the average person in the United States. This information gap contributes to a persistent belief that quality is not a serious national problem.1

In this article, we report results from the Community Quality Index (CQI) study, a collateral study of the Community Tracking Study (CTS).²¹ The CTS, conducted by the Center for Studying Health System Change (CSHSC), monitors changes in health care markets in the United States. The CTS obtains selfreported information from a random sample of the U.S. population on their insurance coverage, patterns of utilization of health care services, and health status. The CSHSC has reported on trends in health care costs, 22 factors affecting the choice of employer-sponsored or public insurance,23 and changes in the structure of managed-care plans.24 However, the CTS lacks detailed information about the implications of these variations in health care markets for the quality of health care. By collaborating with the CSHSC, we were able to assess the extent to which the recommended processes of medical care one critical dimension of quality — are delivered to a representative sample of the U.S. population for a broad spectrum of conditions.

METHODS

RECRUITMENT OF PARTICIPANTS

In 12 metropolitan areas (Boston; Cleveland; Greenville, S.C.; Indianapolis; Lansing, Mich.; Little Rock, Ark.; Miami; Newark, N.J.; Orange County, Calif.; Phoenix, Ariz.; Seattle; and Syracuse, N.Y.), using random-digit-dial telephone surveys, the CTS deliberately recruited enough participants to assess how

structural characteristics in each market (e.g., the penetration of managed care) affect patterns of access to and utilization of health care services. Between October 1998 and August 2000, we recontacted by telephone households that had participated in the CTS interviews. Participants were asked to complete a telephone interview regarding their health history and to provide a listing of all individual or institutional health care providers whom they had seen during the previous two years. Participants who orally agreed to provide access to their medical records were sent written consent forms to sign and return to RAND. Photocopies of the medical records of participants providing written consent were sent to RAND for central abstracting.

RESPONSE RATES

Because of the complex, multistage nature of the study design, several calculations of the response rate are provided. Among the 20,028 adults in the initial sample, 2091 (10 percent) were deemed ineligible, primarily because they had left the area. Among the 17,937 eligible adults, 13,275 (74 percent) participated in the telephone interview regarding their health history, including 863 (7 percent) who had had no visits to a health care provider during the previous two years. Among the 12,412 participants who had had visits, 10,404 (84 percent) agreed orally to provide access to their medical records. We obtained written consent from 7528 (61 percent of those with visits to a provider). Participants reported having seen between 1 and 17 providers (mean, 2.6) during the study period. We obtained at least one record for 6712 (89 percent) of those who returned their consent forms. Overall, we received 84 percent of the records for which we had consent forms; we received all expected records for 4612 of the 6712 participants with consent forms and records (69 percent) and all but one record for 1547 of these participants (23 percent). Sensitivity analyses revealed few differences in results related to the completeness of records, so all participants for whom we obtained at least one record were included in the results we report (37 percent of the sample of eligible adults).

DEVELOPMENT OF INDICATORS OF QUALITY

The indicators of quality used in the study were derived from RAND's Quality Assessment Tools system. ²⁵ RAND staff members selected acute and chronic conditions that represented the leading causes of illness, death, and utilization of health

care in each age group, as well as preventive care related to these causes. For each condition, staff physicians reviewed established national guidelines and the medical literature and proposed indicators of quality for all phases of care or medical functions (screening, diagnosis, treatment, and follow-up). We developed indicators to assess potential problems with the overuse and underuse of key processes. We primarily chose measures of processes as indicators, because they represent the activities that clinicians control most directly, because they do not generally require risk adjustment beyond the specification of eligibility, and because they are consistent with the structure of national guidelines.^{5,26}

Four nine-member, multispecialty expert panels were convened to assess the validity of the indicators proposed by the staff, using the RAND–UCLA modified Delphi method.²⁷ The members of the panels, nominated by the appropriate specialty societies, were diverse with respect to geography, practice setting, and sex. Indicators were rated on a 9-point scale (with 1 denoting not valid and 9 very valid). Only indicators with a median validity score of 7 or higher were included in the Quality Assessment Tools system. This method of selecting indicators is reliable²⁸ and has been shown to have content, construct, and predictive validity in other applications.²⁹⁻³²

The criteria for the selection of conditions, reviews of the literature, the process followed by the panels, and the final indicators have been published elsewhere. 33-36 (Further information on all the quality indicators used in this study is available at http://www.rand.org/health/mcglynn_appa.pdf or from the National Auxiliary Publications Service.*) Table 1 provides a brief description and classifications for a sample of the indicators we used. The classifications enabled us to examine quality from the perspective of what is being done (type of care), why it is being done (function), how it is being delivered (mode), and the nature of the quality problem (underuse or overuse). Results are based on 439 indicators for 30 conditions and preventive care.

HEALTH HISTORY INTERVIEW

We obtained selective information directly from respondents to augment information in their medical records. The health history took an average of 13 minutes to complete. The data obtained in this in-

*See NAPS document no. 05610 for 50 pages of supplementary material. To order, contact NAPS, c/o Microfiche Publications, 248 Hempstead Tpke., West Hempstead, NY 11552.

terview were used to refine the analysis of a respondent's eligibility for inclusion in the analysis or to augment the scoring for 22 of the 439 indicators. For example, we used reports of symptoms from participants with asthma to classify those with moderate-to-severe disease. We augmented scores for influenza or pneumococcal immunizations and screening for cancer on the basis of self-reports.

ABSTRACTING OF CHARTS

We developed computer-assisted abstraction software on a Visual Basic platform (version 6.0, Microsoft). The software allowed the manual abstraction of charts to be tailored to the specific record being reviewed and provided interactive checks of the quality of the data (for consistency and range), calculations (e.g., the determination of the presence of high blood pressure), and classifications (e.g., the determination of drug class) during abstraction.

Data for the study were abstracted by 20 trained registered nurses who had successfully abstracted a complex standard chart after a two-week training program. Charts were abstracted separately for each health care provider of each participant (i.e., at the dyad level). The average time required to abstract a chart for a participant—provider dyad was 50 minutes.

To assess interrater reliability, we re-abstracted charts from a randomly selected 4 percent sample of participants. Average reliability, with the use of the kappa statistic, ranged from substantial to almost perfect³⁷ at three levels: the presence or absence of a given condition (κ =0.83), the participant's eligibility for the process represented by a given indicator (κ =0.76), and scoring of a given indicator (κ =0.80).

STATISTICAL ANALYSIS

We specified the combination of variables necessary to determine whether each participant was or was not eligible for the process specified by each indicator and whether each participant did or did not receive each process or some proportion of it. Each indicator was scored at one of three levels — that of the individual participant, that of the participant—provider dyad, or that of the episode — depending on the nature of the process being evaluated. The level at which an indicator was scored affected the number of times a participant was eligible for the specified process; the resulting number served as the denominator in the calculation of the aggregate score. For participant-level indicators, we gave

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- reperented Anguita-ou	care indicators and Classifications Used in the	Community Qui	ality Index St	udy.*	
Condition†				Security of the Control of the Contr	cores
Alcohol dependence (5 indic	Assessment of alcohol dependence among regular or binge drinkers Treatment referral for persons given a diagnosis of alcohol dependence s) Long-acting agents for patients with frequent use of short-acting beta-agonists Inhaled conticosteroids for patients receiving long-term systemic condition Appropriate follow-up of palpable mass Choice of surgical treatments for stage I or II cancer Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack in gas 40 yr of age Appropriate surgical treatment Appropriate surgical treatment Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with symptomatic cardiovascular disease or transient ischemic attack Carotid Imaging for patients with concentration or action for cardiovascular diseases or transient ischemic attack Carotid Imaging for patients with concentration or action for cardiovascular diseases or action				
Indicator 2	Assessment of alcohol 4		Birth Edinbonder	See State of the Section Control of the Secti	
	among regular or binge drinker		Diagnosi on	s History	Underuse
Indicator 4	Treatment referral for persons giver	no For-built	研究 经金额 经		
Asthma (25 indicators)	diagnosis of alcohol dependenc				ier Underuse
n SAN 1970 NO Carana a a sugaran calan	Control of Victoria Control of the C				
Indicator 4	rrequent use of short-acting bet			t Medication	Underuse
Indicator 6	Inhaled corticosteroids for patients	FI		Encounter or other intervention Medication Medication Underuse Underuse Underuse Underuse Underuse Underuse Underuse Or radiography Underuse	
	receiving long-term systemic cou	ror enronic - condition	Treatment n	t Medication	Underuse
Breast cancer (9 indicators)					
Indicator 1	Appropriate follow-up of palpable mass		Diagnosis	Laboratory testing	g Underuse
ndicator 5	stage or cancer	For chronic	Treatment	was a production of the production of the state of the st	TO STREET STATES
erebrovascular disease (10 inc	dicators)				
ndicator 4	Antiplatelet therapy for noncardiac stroke or transient ischemic attacl		Treatment	Medication	Underuse
ndicator 5	symptomatic cardiovascular die-	For chronic	Commission of the State	Laboratory testing or radiography	Underuse
olorectal cancer (12 indicators)				
dicator 1	Screening for high-risk patients start-	Preventive	Screening	Laboratory testing	Underuse
dicator 7				or radiography	
ngestive heart failure (36 indi			Treatment	Surgery	Underuse
dicator 1	. Walnut to a contract of the	no i debak da eda da.			
licator 32	medical therapy	For chronic condition	Diagnosis I	Laboratory testing or radiography	Underuse
	gestive heart failure and an elec-		Treatment N	Medication	Underuse
onary artery disease (37 indic					
icator 3	Counseling on smoking cessation		Treatment C		Underuse 🧍
cator 11	Avoidance of nifedipine for patients with an acute myocardial infarction	For chronic 7	reatment N		Overuse
petes (13 indicators)	y	condition			
cator 9	Diet and exercise course!	<u>1</u> 2-34000000000000000000000000000000000000	Algeria Salamana a a a a	gallationege saving as the case on a	
	A CALCUSE COURSEIING	For chronic T condition	reatment Co		Underuse
cator 12	ACE inhibitors for patients with proteinuria		reatment M	education edication (Jnderuse

ble 1. (Continued:)	Description of Selected Indicator	Cla	assification fo	r Aggregate Scores	
ondition	Description of others.	Type of Care	Function	Mode	Problem with Quality
eadache (21 indicators)	The state of the s	e o Awar i So	जन्म - वेहामान क्षेत्रीती	aboratory testing	lindenise
dicator 11	CT or MRI for patients with new-onset headache and an abnormal neuro- logic examination	Acute	Diagnosis	or radiography	
dicator 15	Use of appropriate first-line agents for patients with acute migraine	Acute	Treatment I	Medication	Overuse
lip fracture (9 indicators)	The first of the second state of the second st		a tavasijai (a		Underuse
ndicator:6	Prophylactic antibiotics given on day of hip-repair surgery	Acute	Treatment		Underuse
ndicator 7	Prophylactic antithrombotic drugs given on admission for patients with hip fracture	Acute	Treatment	Medication	Olideinsc
Hyperlipidemia (7 indicators)		province (and	Treatment	Medication	Underuse
ndicator 4	Treatment of high LDL cholesterol levels in patients with coronary artery disease	For chronic condition	ireamen.		
Hypertension (27 indicators)	descriptions of a consistence of a service o				11
indicator 16	Lifestyle modification for patients with mild hypertension	For chronic condition	Lauren managen semmas en en 2000.	Counseling or education	Underuse
Indicator 18	Pharmacotherapy for uncontrolled mild hypertension	For chronic condition	akan atau awakewa aktiba katib	Medication	Underuse
Indicator 27	Change in treatment when blood pres sure is persistently uncontrolled	 For chronic condition 	Follow-up	Medication	Underuse
Acute low back pain (6 indicators)		permanuta (1850	enger pleifen i fil fil		Underuse
Indicator 1	Rule out cancer, fracture, infection, cauda equina syndrome, and neurologic causes	Acute state and a second secon	Diagnosis	History	
Indicator 6	Avoidance of prolonged bed rest	Acute	Treatment	Other	Overuse
Preventive care (38 indicators)		operation of the Section of the Control of the Cont	Series and despe	onere asserbit	James Marise
Indicator 1	Screening for problem drinking	Preventive	医精神经外外外的 对一位	History	g Underuse
Indicator 2	Mammographic screening for breast cancer			Laboratory testin or radiograph	iy San roher onsektir
Indicator 3	Screening for colorectal cancer in persons at average risk	Preventive		Laboratory testin or radiograph	ny salata
Indicator 8	Influenza vaccine for persons ≥65 yr of age	Preventive		t Immunization	Underuse
Indicator 21	. HIV testing for those at risk	Preventive	Screening	g Laboratory testir or radiograp	hy, control
Indicator 25	Screening for cervical cancer	Preventive	Screenin	g Laboratory testii or radiograp	hy sa tanàna ao ao ao ao ao ao ao ao
Indicator 29	Smoking status documented	Preventive	સૈક્ષિક ઉદ્યુપ્તિક કાર્યાનની વિજેશ છ	g History	Underus
Indicator 31	Annual advice for smokers to quit smoking	Preventive	Treatmen	nt Counseling or education	Underus

Condition						
	Description of Selected Indicator	Classification for Aggregate Scores				
Sexually transmitted diseases (26 indicators)		Type of Care	Function	Mode	Problem with Quali	
	Chlamydia screening for high-risk women HIV screening in patients with sexual-	American Section (Section 1971)		STATE OF THE LOUIS AND	Alah Messi Massansi Sana	
	women	Preventive	Screening	Laboratory testing or radiography	Underuse	

^{*} ACE denotes angiotensin-converting enzyme, CT computed tomography, MRI magnetic resonance imaging, LDL low-density lipoprotein, and

the participant a score of "pass" if at least one of his or her health care providers had delivered the indicated care (e.g., influenza vaccination). For indicators scored at the level of the participant-provider dyad (e.g., smoking status noted in the chart), we scored every dyad separately, so the number of times the participant was counted in the denominator depended on the number of providers who saw the participant and could have performed the specified process. For indicators scored at the episode level (e.g., follow-up after hospitalization for an exacerbation of asthma), we scored every event rendering the participant eligible for the specified process and involving any of the participant's providers, so the number of eligibility events depended on the number of episodes that occurred.

In order to produce aggregate scores, we divided all instances in which recommended care was delivered by the number of times participants were eligible for indicators in the category. For example, Table 1 presents information about seven of the indicators for acute care; the number of times participants were eligible for these indicators would constitute the denominator for the acute care score. The results are presented as proportions, theoretically ranging in value from 0 to 100 percent. We used the bootstrap method to estimate standard errors directly for all the aggregate scores.38

Because everyone in the initial sample for the CQI study had participated in the CTS, we had a rich set of variables for assessing nonresponse. We used logistic-regression analysis to estimate the relations between individual characteristics (age, sex, race, educational level, income, self-reported level of use of physicians and hospitals, insurance status, and

health status) and participation in the study. In general, participants tended to be older than nonparticipants (P<0.001) and were more likely than nonparticipants to be female (P<0.001) and white (P<0.001), with higher levels of education (P<0.001) and income (P<0.001). They were also more likely to have used health care services (P<0.001) and to be in other than excellent health (P=0.03). We used the coefficients from the regression equation to adjust the scores for nonresponse, and we weighted the data for the participants to be representative of the population from which they were drawn.

RESULTS

CHARACTERISTICS OF THE PARTICIPANTS

Table 2 summarizes the characteristics of the participants; these characteristics differ from population averages but parallel the profile of persons receiving medical care. For example, the average age of patients in the National Ambulatory Medical Care Survey³⁹ is 44.7 years. Women have higher rates of visits than men (319.9 vs. 234.9 visits per 100 persons per year), and whites have higher rates of visits than blacks (293.2 vs. 210.7 visits per 100 persons per year).39 Participants were well educated. Fortythree percent had one or more of the chronic conditions we assessed, and 34 percent had one or more of the acute conditions. Preventive care was assessed for all participants; in addition, participants' care was assessed for 1.5 chronic or acute conditions, on average, for a total of 2.5 (range, 1 to 13). Participants were included in the overall denominator an average of 16 times (range, 2 to 304).

[†] The number of indicators given in parentheses after each condition is the total number of indicators of quality of care for that condition; the

ANALYSIS OF CARE DELIVERED

Tables 3, 4, and 5 show the number of indicators included in the aggregate score, the number of persons eligible for one or more processes within the category, the number of times participants in the sample were eligible for indicators, and the weighted mean proportion (and 95 percent confidence interval) of recommended processes that were delivered.

Overall, participants received 54.9 percent of recommended care (95 percent confidence interval, 54.3 to 55.5) (Table 3). This level of performance was similar in the areas of preventive care, acute care, and care for chronic conditions. The level of performance according to the particular medical function ranged from 52.2 percent (95 percent confidence interval, 51.3 to 53.2) for screening to 58.5 percent (95 percent confidence interval, 56.6 to 60.4) for follow-up care.

"Mode" refers to the mechanism of care delivery required for the provision of the indicated process. Analysis of performance in terms of mode may identify areas in which system-wide interventions could offer solutions to problems of quality, such as improved methods for ordering, processing, and communicating laboratory results. We found greater variation among modes than among functions in adherence to the processes we studied (Table 4). Care requiring an encounter or other intervention (e.g., the annual visit recommended for patients with hypertension) had the highest rates of adherence (73.4 percent [95 percent confidence interval, 71.5 to 75.3]), and processes involving counseling or education (e.g., advising smokers with chronic obstructive pulmonary disease to quit smoking) had the lowest rates of adherence (18.3 percent [95 percent confidence interval, 16.7 to 20.0]). All pairwise differences were statistically significant at P<0.001 except those between the prescribing of medication and care requiring an encounter or other intervention (P=0.02), physical examination and immunization (P=0.001), surgery and immunization (P=0.004), and surgery and physical examination (P=0.05). The difference between surgery and laboratory testing or radiography was not significant (P=0.39).

PROBLEMS WITH QUALITY OF CARE

We also classified indicators according to the problem with quality that was deemed most likely to occur, and we found greater problems with underuse (46.3 percent of participants did not receive recom-

Table 2. Characteristics of the 6712	? Participants.*
Characteristic	Value
Age (yr) Mean Range	45.5±0.2 18–97
Female sex (%)	59.6±0.006
Nonwhite race (%)	₹ 18.6±0.005
Education (yr)	13.7±0.03
≥1 Chronic conditions (%)	44.7±0.006
≥1 Acute conditions (%)	36.3±0.006
No. of conditions and preventive which participants were e Mean Range	care for ligible 2.5±0.02 1–13
No. of times participants eligible indicators† Mean Range	for 15.8±0.17 2–304

* Plus-minus values are means or percentages ±SE.
† The number of times a participant is eligible for an indicator is a function of the level at which the indicator is scored (participant, participant-provider dyad, or episode), the number of participants eligible for the specified process, and the number of indicators in the aggregate-score category.

mended care [95 percent confidence interval, 45.8 to 46.8]) than with overuse (11.3 percent of participants received care that was not recommended and was potentially harmful [95 percent confidence interval, 10.2 to 12.4]).

VARIATIONS IN QUALITY

Table 5 shows substantial variability in the quality-of-care scores for the 25 conditions for which at least 100 persons were eligible for analysis. Persons with senile cataracts received 78.7 percent of the recommended care (95 percent confidence interval, 73.3 to 84.2); persons with alcohol dependence received 10.5 percent of the recommended care (95 percent confidence interval, 6.8 to 14.6). The aggregate scores for individual conditions were generally not sensitive to the presence or absence of any single indicator of quality.

DISCUSSION

Overall, participants received about half of the recommended processes involved in care. These defi-

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No. of Participants Solution Was Met (95% CI)* Total No. of Percentage of Times Indicator Recommended Care Received Was Met (95% CI)*	Table 3. Adh of Care and I	erence to Qual Function.	lity Indicators,	Overall and Accord	ding to Type
	Variable		Participants	Times Indicator Eligibility	Recommended Care Received

Variable	Indicators	Eligible	Was Met	Care Received (95% CI)*
Overall care	439	6712	98,649	54.9 (54.3–55.5)
Type of care	7 A. H. L.			J4.3 (34.3-33.5)
Preventive	38	6711	55,268	54.9 (54.2–55.6)
Acute Chronic	153 248	2318 3387	19,815	53.5 (52.0–55.0)
Function			23,566	56.1 (55.0–57.3)
Screening	41	6711	39,486	
Diagnosis	178	6217	29,679	52.2 (51.3–53.2) 55.7 (54.5–56.8)
Treatment	173	6707	23,019	57.5 (56.5–58.4)

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Follow-up

				The state of the s
Mode	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)*
Encounter or othe intervention	er 30	2843	4,329	73.4 (71.5–75.3
Medication	95	2964	8,389	68.6 (67.0–70.3)
Immunization	8	6700	1805 Maria Both Commission Co.	65.7 (64.3–67.0)
Physical exam- ination	67	6217		52.9 (61.8–64.0)
Laboratory testing or radiography	131	5352	18,605 6	il.7 (60.4–63.0)
Surgery	21	244	312 5	6.9 (51.3–62.5)
listory	64	6711	AND VERMEN IN LOAD PERM	3.4 (42.4–44.3)
Counseling or education	23	2838		8.3 (16.7–20.0)

^{*} CI denotes confidence interval. All pairwise differences were statistically significant at P<0.001 except those between medication and encounter or other intervention (P=0.02), physical examination and immunization (P=0.001), surgery and immunization (P=0.004), and surgery and physical examination (P=0.05). The difference between surgery and laboratory testing or radiography was not significant (P=0.39).

cits in care have important implications for the health of the American public. For example, only 24 percent of participants in our study who had diabetes received three or more glycosylated hemoglobin tests over a two-year period. This finding parallels the finding by Saaddine and colleagues that 29 percent of adults with diabetes who participated in the nationally representative Behavioral Risk Factor Surveillance System reported having their blood sugar tested during the previous year. 18 This routine monitoring is essential to the assessment of the effectiveness of treatment, to ensuring appropriate responses to poor glycemic control, and to the identification of complications of the disease at an early stage so that serious consequences may be prevented. In the United Kingdom Prospective Diabetes Study, tight blood glucose control and biannual monitoring decreased the risk of microvascular complications by 25 percent.40

In our study, persons with hypertension received 64.7 percent of the recommended care (95 percent confidence interval, 62.6 to 66.7). We have previously demonstrated a link between blood-pressure control and adherence to process-related measures of quality of care for hypertension. ⁴¹ Persons whose blood pressure is persistently above normal are at increased risk for heart disease, stroke, and death. ⁴² Poor blood-pressure control contributes to more than 68,000 preventable deaths annually. ⁴³

Overall, 68.0 percent (95 percent confidence interval, 64.2 to 71.8) of the recommended care for coronary artery disease was received, but only 45 percent of persons presenting with a myocardial infarction received beta-blockers, which reduce the risk of death by 13 percent during the first week of treatment and by 23 percent over the long term. 44 Only 61 percent of participants with a myocardial infarction who were appropriate candidates for aspirin therapy received aspirin, which has been shown in randomized trials to reduce the risk of death from vascular causes by 15 percent, to reduce the risk of nonfatal myocardial infarction by 30 percent, and to reduce the risk of nonfatal stroke by 40 percent. 45

Deficits in processes involved in primary and secondary preventive care are also associated with preventable deaths. Among elderly participants, only 64 percent had received or been offered a pneumococcal vaccine; nearly 10,000 deaths from pneumonia could be prevented annually by appropriate

58.5 (56.6-60.4)

^{*} CI denotes confidence interval.

vaccinations. ⁴³ About 38 percent of participants had been screened for colorectal cancer; annual fecal occult-blood tests could prevent about 9600 deaths annually. ⁴³

Nonresponse bias is a potential limitation of the study. Because the sample we analyzed included 37 percent of the eligible adults, the results are likely to be biased, but the direction of that bias is not clear. For example, because our participants were more likely to use the health care system than were eligible persons who did not participate in the study, our results may be biased toward an underestimation of deficits in quality related to underuse.

The study relied primarily on the review of medical records to score indicators, which may lead some to conclude that we have identified problems with documentation rather than quality. This issue has been examined in studies that compared process-based quality scores using standardized patients, vignettes, and abstraction of medical records46 and studies that compared standardized patients with audiotapes of encounters. 47 Overall, the process scores among the four conditions studied were 5 percentage points lower with the use of medical records than with the use of vignettes and 10 percentage points lower with the use of medical records than with the use of standardized patients. About two thirds of the disagreement between data from standardized patients and data from audiotapes was attributable to reports by standardized patients that they received care processes that were not confirmed by audiotape. A related study reported a false positive rate of 6.4 percent in medical-record documentation, with the highest false positive rates found for physical examination and elements of the diagnostic process. 48 Thus, our scores might have been as much as 10 percentage points higher if we had used a different method of obtaining data. We used the interview about the participant's health history to partially offset this effect. For example, among elderly participants, only 15 percent had a note in any chart indicating that an influenza vaccination had been received, but 85 percent reported having received one. In general, the inclusion of self-reported data improved scores.

Our results indicate that, on average, Americans receive about half of recommended medical care processes. Although this point estimate of the size of the quality problem may continue to be debated, the gap between what we know works and what is

able 5. Adherence to Qu	uality Indicate	ors, Accordin	g to Conditi	on.*	
Condition		No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)	· · · · · · · · · · · · · · · · · · ·
· ar american asserting (SPAS)	10	159 %	602	78.7 (73.3–84.2)	, T. W.
Senile cataract	9	192	202	75.7 (69.9-81.4	
Breast cancer Prenatal care	39	134	2920	73.0 (69.5–76.6)
BOARD LANGUAGE COLORS AND	⊕3446.48## 6	489	3391	68.5 (66.4–70.5)
Low back pain	37	410	2083	68.0 (64.2–71.8	3)
Coronary artery disease	10 (1984), 275(1975) 15. 964(1987)			64.7 (62.6–66.	ር 35 / 7 \
Hypertension	27	1973	6643	63.9 (55.4–72.	12.5
Congestive heart failu	re 36 s	104	1438	Berker carrier assistances and	
Cerebrovascular	10	101	210	59.1 (49.7–68.	1)
disease	20	169	1340	58.0 (51.7–64	4)
Chronic obstructive pulmonary diseas			News (S		
Depression	14	770	3011	57.7 (55.2–60	17.5
Orthopedic condition	ns 10	302	590	SECULEAR CONTRACTOR	,
Osteoarthritis	3 3	598	648	Secretary of August St. #1505459905425	
Colorectal cancer	12	231	329	53.9 (47.5–6	0.4
Asthma	25	260	2337	2 53.5 (50.0–5	7.0
Benign prostatic hyp	ner- 5	138	14	7 53.0 (43.6–6	2.5
plasia				3 48.6 (44.1–5	3 7
Hyperlipidemia	7	519	secopysenesse)	management a warmer of the test in Court	150
Diabetes mellitus	13	488	per appleases	45.0 (42.1	
Headache	21	71: The service was fact the	salastasiisi	and the second second second	5550
Urinary tract infect	ion 13	45	Self School Self-	aggles trans to the extra	
Community-acquir	_	14	4 2'	91 39.0 (32.1-	-t.J.
pneumonia	and coming	. 4)	0 21	46 36.7 (33.8-	39
Sexually transmitted diseases or value	CU DESCRIPTION OF COMME				
Dyspepsia and pe	And And Comment	g 2	78 2	87 32.7 (26.4	-39
ulcer disease	。 1. 图 1. 80 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			407 24.7 (18.4	3(
Atrial fibrillation	1	Y. 主要 (1991)	T BESTER	distribution and the party of	
Hip fracture	an and an	eles sonstille		1988年 - 1985 / AS	20.0
Alcohol depende	nce	5 2	80 . 7	036 10.5 (6.8-	

^{*} Condition-specific scores are not reported for management of pain due to cancer and its palliation, management of symptoms of menopause, hysterectomy, prostate cancer, and cesarean section, because fewer than 100 people were eligible for analysis of these categories. CI denotes confidence interval.

actually done is substantial enough to warrant attention. These deficits, which pose serious threats to the health and well-being of the U.S. public, persist despite initiatives by both the federal government and private health care delivery systems to improve care.

What can we do to break through this impasse? Given the complexity and diversity of the health care system, there will be no simple solution. A key component of any solution, however, is the routine availability of information on performance at all levels. Making such information available will require a major overhaul of our current health information systems, with a focus on automating the entry and retrieval of key data for clinical decision making and for the measurement and reporting of quality.⁴⁹

Establishing a national base line for performance makes it possible to assess the effect of policy changes and to evaluate large-scale national, regional, state, or local efforts to improve quality.

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The Quality of Children's Health Care Matters — Time to Pay Attention

James M. Perrin, M.D., and Charles J. Homer, M.D., M.P.H.

High-quality health care matters for all children - and is critically important for some. In many ways, health care for children serves the same function as health care for adults. For example, the incidence of chronic illness in children is increasing, resulting in a substantial illness burden with a substantial cost. How well chronic conditions are managed profoundly influences both short-term and long-term outcomes, not only for common diseases such as asthma but also for rarer conditions such as cancer, cystic fibrosis, and sickle cell disease.2

Many aspects of children's health care have no parallel in adult health services.3 The disproportionate rates of poverty among children and adolescents mean that children's health services must address health needs despite limited resources. Because children are dependent on caregivers and community resources, providers of child health care must enhance the competency of these caregivers and coordinate a broad array of community services. Children's health care settings typically involve developmental surveillance; the identification of sensory, learning, and behavioral disorders; and monitoring for family violence

and child abuse. Optimally, such programs provide evidence-informed counseling that promotes positive behaviors related to individual health, family functioning, and psychological and developmental well-being - all of which are beyond traditional health care services - with effects that last for the rest of a child's life.

The article by Mangione-Smith et al.4 in this issue of the Journal, although addressing traditional health care services and ambulatory care only, nonetheless presents sobering findings. The authors examined hundreds of indicators of quality, developed according to complex but well-established methods from RAND and UCLA, emphasizing the most common reasons for which children use the health care system. They intentionally studied a full spectrum of ambulatory services - at least within the traditional health care domains of preventive care, care for acute conditions, and care for chronic conditions for children of all ages.

Their observations are shocking: the right services appear to be carried out less than half the time. Services are not delivered when they should be, or they are delivered when they should not

be. In general, the same dismal story was apparent in all aspects of pediatric ambulatory care examined.

But can we be confident that these results accurately reflect the quality of services currently delivered to children? The research has limitations. The percentage of parents willing to allow the researchers access to their child's medical information was low and probably not random. The methods, by necessity, excluded less-prevalent conditions, even though such conditions may carry a higher risk and may account for substantial rates of disability and death. In addition, the study did not address the broader public health functions of child health care we describe above.

Mangione-Smith et al. relied on the written medical record. The much higher adherence rate for medication use (which clinicians are more likely to chart accurately) than for other modes of care might suggest that the lower adherence rates reflect failures in charting rather than in performance. In addition, the panels developing the quality criteria did so nearly a decade ago, and the data reported are from the period 1996 through 2000.

The investigators worked hard to minimize the effect of potential shortcomings on the validity of their overall findings. They used sophisticated statistical methods to adjust for nonresponse. They focused on indicators likely to be documented in medical records. The consistency of the findings and the care with which the study was done overall indicate that the general observations are indeed valid. Although one could challenge the precise 46.5% value for the percentage of overall care delivered, one cannot avoid the main observation that there exists a yawning chasm in the quality of health care provided to children.

The prevalent view of children's health care is that problems related to quality occur much less often than in other fields. The dramatic improvements in outcomes — the near-elimination of many vaccine-preventable illnesses and vast improvements in the survival of children with severe conditions such as cancer or congenital heart disease — perhaps have lulled us into the belief that all is well. But these new data, together with those from many other studies across both inpatient and outpatient settings, make it clear that problems with the quality of children's care are

as severe as those occurring elsewhere in our health care system. 5-9

Improvement of the performance of the children's health care system will require systemwide change; entreaties to hard-working and deeply caring pediatricians, family physicians, nurses, and hospital staff to work harder and care more will not succeed by themselves. Effecting change will require leadership across all levels and systems involved in children's health care and a wholehearted commitment by those who deliver care, pay for care, and receive care. Leaders must recognize that the current system does not meet children's needs and must take action.

A complete application to pediatric care of the approaches outlined by the Institute of Medicine in its report Crossing the Quality Chasm,10 which are increasingly applied by Medicare and other agencies, might begin to address the glaring deficiencies noted by Mangione-Smith et al. These approaches include a systematic focus on patients with chronic conditions, the effective application of health information technology, an emphasis on patient-centered and family-centered care, organizational transparency and improved capability, and the more appropriate alignment of incentives coupled with the use of valid quality measures. Publicly financed insurers and health plans for children have given much less attention to quality than has Medicare - in large part because Medicaid and the State Children's Health Insurance Program (SCHIP) are joint federalstate programs. Indeed, states have been highly reluctant to consider using common health care standards in the Medicaid and SCHIP programs. SCHIP is currently up for renewal; fortunately, some of the recent bills call for enhanced efforts toward quality of care in SCHIP and companion Medicaid programs.11 These proposals include the development of common measures; support for children's health care information technology; and execution of demonstration projects addressing obesity and the medical home.

This concerted effort is necessary but not sufficient to address the broader context and role of children's health care and to address the most pressing challenges of diagnosis and treatment—such as for obesity, mental health, and disparities in access to care. Even more innovation is needed in new models of care and in the substantive redesign of the organization, human re-

sources, finance, and delivery of health services underlying the children's health care system. 12,13 Although these strategies extend far beyond the data in the article by Mangione-Smith et al., the data themselves may provide a clarion call for action.

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INSTITUTE OF MEDICINE

Shaping the Future for Health

CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY

the U.S. health care delivery system does not provide consistent, high-quality medical care to all people. Americans should be able to count on receiving care that meets their needs and is based on the best scientific knowledge--yet there is strong evidence that this frequently is not the case. Health care harms patients too frequently and routinely fails to deliver its potential benefits. Indeed, between the health care that we now have and the health care that we could have lies not just a gap, but a chasm.

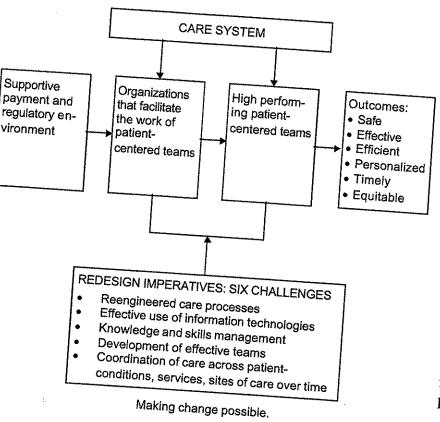
A number of factors have combined to create this chasm. Medical science and technology have advanced at an unprecedented rate during the past half-century. In tandem has come growing complexity of health care, which today is characterized by more to know, more to do, more to manage, more to watch, and more people involved than ever before. Faced with such rapid changes, the nation's health care delivery system has fallen far short in its ability to translate knowledge into practice and to apply new technology safely and appropriately. And if the system cannot consistently deliver today's science and technology, it is even less prepared to respond to the extraordinary advances that surely will emerge during the coming decades.

The public's health care needs have changed as well. Americans are living longer, due at least in part to advances in medical science and technology, and with this aging population comes an increase in the incidence and prevalence of chronic conditions. Such conditions, including heart disease, diabetes, and asthma, are now the leading cause of illness, disability, and death. But today's health system remains overly devoted to dealing with acute, episodic care needs. There is a dearth of clinical programs with the multidisciplinary infrastructure required to provide the full complement of services needed by people with common chronic conditions.

The health care delivery system also is poorly organized to meet the challenges at hand. The delivery of care often is overly complex and uncoordinated, requiring steps and patient "handoffs" that slow down care and decrease rather than improve safety. These cumbersome processes waste resources; leave unaccountable voids in coverage; lead to loss of information;



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and fail to build on the strengths of all health professionals involved to ensure that care is appropriate, timely, and safe. Organizational problems are particularly apparent regarding chronic conditions. The fact that more than 40 percent of people with chronic conditions have more than one such condition argues strongly for more sophisticated mechanisms to coordinate care. Yet health care organizations, hospitals, and physician groups typically operate as separate "silos," acting without the benefit of complete information about the patient's condition, medical history, services provided in other settings, or medications provided by other clinicians.

Strategy for Reinventing the System

Bringing state-of-the-art care to all Americans in every community will require a fundamental, sweeping redesign of the entire health system, according to a report by the Institute of Medicine (IOM), an arm of the National Academy of Sciences. Crossing the Quality Chasm: A New Health System for the 21st Century, prepared by the IOM's Committee on the Quality of Health Care in America and released in March 2001, concludes that merely making incremental improvements in current systems of care will not suffice.

The committee already has spoken to one urgent care problem--patient safety--in a 1999 report titled To Err is Human: Building a Safer Health System. Concluding that tens of thousands of Americans die each year as a result of preventable mistakes in their care, the report lays out a comprehensive strategy by which government, health care providers, industry, and consumers can reduce

Crossing the Quality Chasm focuses more broadly on how the health system can be reinvented to foster innovation and improve the delivery of care. Toward this goal, the committee presents a comprehensive strategy and action plan

Six Aims for Improvement

Advances must begin with all health care constituencies--health professionals, federal and state policy makers, public and private purchasers of care, regulators, organization managers and governing boards, and consumers--committing to a 2

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national statement of purpose for the health care system as a whole. In making this commitment, the parties would accept as their explicit purpose "to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States." The parties also would adopt a shared vision of six specific aims for improvement. These aims are built around the core need for health care to be:

• Safe: avoiding injuries to patients from the care that is intended to help

Effective: providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.

• Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.

• *Timely*: reducing waits and sometimes harmful delays for both those who receive and those who give care.

• Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy.

• Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

A health care system that achieves major gains in these six areas would be far better at meeting patient needs. Patients would experience care that is safer, more reliable, more responsive to their needs, more integrated, and more available, and they could count on receiving the full array of preventive, acute, and chronic services that are likely to prove beneficial. Clinicians and other health workers also would benefit through their increased satisfaction at being better able to do their jobs and thereby bring improved health, greater longevity, less pain and suffering, and increased personal productivity to those who receive their care.

Ten Rules for Redesign

To help in achieving these improvement aims, the committee deemed that it would be neither useful nor possible to specify a blueprint for 21st-century health care delivery systems. Imagination abounds at all levels, and all promising routes for innovation should be encouraged. At the same time, the committee formulated a set of ten simple rules, or general principles, to inform efforts to redesign the health system. These rules are:

1. Care is based on continuous healing relationships. Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This implies that the health care system must be responsive at all times, and access to care should be provided over the Internet, by telephone, and by other means in addition to in-person visits.

2. Care is customized according to patient needs and values. The system should be designed to meet the most common types of needs, but should have the capability to respond to individual patient choices and preferences.

3. The patient is the source of control. Patients should be given the nec-

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Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

essary information and opportunity to exercise the degree of control they choose over health care decisions that affect them. The system should be able to accommodate differences in patient preferences and encourage shared decision making.

- 4. Knowledge is shared and information flows freely. Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.
- 5. Decision making is evidence-based. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.
- 6. Safety is a system property. Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.
- 7. Transparency is necessary. The system should make available to patients and their families information that enables them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.
- 8. Needs are anticipated. The system should anticipate patient needs, rather than simply react to events.
- 9. Waste is continuously decreased. The system should not waste resources or patient time.
- 10. Cooperation among clinicians is a priority. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Taking the First Steps

To initiate the process of change, Congress should establish a Health Care Quality Innovation Fund--roughly \$1 billion for use over three to five years to help produce a public-domain portfolio of programs, tools, and technologies of wide-spread applicability, and to help communicate the need for rapid and significant change throughout the health system. Some of the projects funded should be targeted at achieving the six aims of improvement.

The committee also calls for immediate attention on developing care processes for the common health conditions, most of them chronic; that afflict great numbers of people. The federal Agency for Healthcare Research and Quality (AHRQ) should identify 15 or more common priority conditions. (The agency has requested guidance from the IOM on selection of these conditions, and the Institute expects to issue its report in September 2002.) The AHRQ then should work with various stakeholders in the health community to develop strategies and action plans to improve care for each of these priority conditions over a five-year period.

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Changing the Environment

Redesigning the health care delivery system also will require changing the structures and processes of the environment in which health professionals and organizations function. Such changes need to occur in four main areas:

• Applying evidence to health care delivery. Scientific knowledge about best care is not applied systematically or expeditiously to clinical practice. It now takes an average of 17 years for new knowledge generated by randomized controlled trails to be incorporated into practice, and even then application is highly uneven. The committee therefore recommends that the Department of Health and Human Services establish a comprehensive program aimed at making scientific evidence more useful and more accessible to clinicians and patients.

It is critical that leadership from the private sector, both professional and other health care leaders and consumer representatives, be involved in all aspects of this effort to ensure its applicability and acceptability to clinicians and patients. The infrastructure developed through this public-private partnership should focus initially on priority conditions. Efforts should include analysis and synthesis of the medical evidence, delineation of specific practice guidelines, identification of best practices in the design of care processes, dissemination of the evidence and guidelines to the professional communities and the general public, development of support tools to help clinicians and patients in applying evidence and making decisions, establishment of goals for improvement in care processes and outcomes, and development of measures for assessing quality of care.

• Using information technology. Information technology, including the Internet, holds enormous potential for transforming the health care delivery system, which today remains relatively untouched by the revolution that has swept nearly every other aspect of society. Central to many information technology applications is the automation of patient-specific clinical information. Such information typically is dispersed in a collection of paper records, which often are poorly organized, illegible, and not easy to retrieve, making it nearly impossible to manage various illnesses, especially chronic conditions, that require frequent monitoring and ongoing patient support. Many patients also could have their needs met more quickly and at a lower cost if they could communicate with health professionals through e-mail. In addition, the use of automated systems for ordering medications can reduce errors in prescribing and dosing drugs, and computerized reminders can help both patients and clinicians identify needed services.

The challenges of applying information technology should not be underestimated, however. Health care is undoubtedly one of the most, if not the most, complex sectors of the economy. Sizable capital investments and multiyear commitments to building systems will be needed. Widespread adoption of many information technology applications also will require behavioral adaptations on the part of large numbers of clinicians, organizations, and patients. Thus, the committee calls for a nationwide commitment of all stakeholders to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education. This commitment should lead to the elimination of most handwritten clinical data by the end of the decade.

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• Aligning payment policies with quality improvement. Although payment is not the only factor that influences provider and patient behavior, it is an important one. The committee calls for all purchasers, both public and private, to carefully reexamine their payment policies to remove barriers that impede quality improvement and build in stronger incentives for quality enhancement. Clinicians should be adequately compensated for taking good care of all types of patients, neither gaining nor losing financially for caring for sicker patients or those with more complicated conditions. Payment methods also should provide an opportunity for providers to share in the benefits of quality improvement, provide an opportunity for consumers and purchasers to recognize quality differences in health care and direct their decisions accordingly, align financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes, and enable providers to coordinate care for patients across settings and over time.

To assist purchasers in their redesign of payment policies, the federal government, with input from the private sector, should develop a program to identify, pilot test, and evaluate various options for better aligning payment methods with quality improvement goals. Examples of possible means of achieving this end include blended methods of payment designed to counter the disadvantages of one payment method with the advantages of another, multiyear contracts, payment modifications to encourage use of electronic interaction among clinicians and between clinicians and patients, and bundled payments for priority conditions.

Preparing the workforce. Health care is not just another service industry. Its fundamental nature is characterized by people taking care of other people in times of need and stress. Stable, trusting relationships between a patient and the people providing care can be critical to healing or managing an illness. Therefore, the importance of adequately preparing the workforce to make a smooth transition into a thoroughly revamped health care system cannot be un-

Three approaches can be taken to support the workforce in this transition. One approach is to redesign the way health professionals are trained to emphasize the six aims for improvement, which will mean placing more stress on teaching evidence-based practice and providing more opportunities for interdisciplinary training. Second is to modify the ways in which health professionals are regulated and accredited to facilitate needed changes in care delivery. Third is to use the liability system to support changes in care delivery while preserving its role in ensuring accountability among health professionals and organizations. All of these approaches likely will prove valuable, but key questions remain about each. The federal government and professional associations need to study these approaches to better ascertain how they can best contribute to ensuring the strong workforce that will be at the center of the health care system of the 21st century.

No Better Time

Now is the right time to begin work on reinventing the nation's health care delivery system. Technological advances are making it possible to accomplish things today that were impossible only a few years ago. Health professionals and organizations, policy makers, and patients are becoming all too painfully aware of the shortcomings of the nation's current system and of the importance of finding radically new and better approaches to meeting the health care needs of all Americans. Although Crossing the Quality Chasm does not offer a simple prescription-there is none--it does provide a vision of what is possible and the path that can be taken. It will not be an easy road, but it will be most worthwhile.

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For More Information...

Copies of Crossing the Quality Chasm: A New Health System for the 21st Century are available for sale from the National Academy Press; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP home page at www.nap.edu. The full text of this report is available at http://www.nap.edu/books/0309072808/html/

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